

### **REMARKS**

Claims 46-71 are pending for examination with claims 46, 53, 59, and 65 being independent claims. Claims 46, 53, 59 and 65 have been amended to clarify some aspects of the claimed inventions. No new matter has been added.

Applicants acknowledge the courtesies extended to James M. Hanifin, Jr. during the telephone interview on May 19, 2004 with Examiner Bonderer and Examiner Philogene. The substance of the discussion during the interview is incorporated into the following remarks.

Applicants respectfully traverse each of the rejections presented in the Office Action of January 9, 2004 for the reasons set forth in their prior response of December 23, 2003 and the declaration of Stephan N. Eldridge (hereafter the "Eldridge Declaration") submitted therewith, which are incorporated herein by reference.

#### **Allowable Subject Matter**

Applicants acknowledge the Examiner's indication that claims 47-49 and 67 would be allowable if rewritten in independent form including all of the limitations of their respective base claim and any intervening claims. These claims have not been rewritten in independent form because these depend from claims believed to be allowable as discussed below.

#### **Rejections Under 35 U.S.C. § 112**

Claim 71 stands rejected under 35 U.S.C. §112, second paragraph, as being indefinite on the basis that the recitation "the margin section" lacks an antecedent basis. Applicants respectfully disagree. In particular, the recitation "the margin section" finds a proper antecedent basis in claim 65 from which it depends. Accordingly, the §112, ¶2, rejection of claim 71 is improper and should be withdrawn.

#### **Rejections Under 35 U.S.C. § 102**

Claims 46, 50, 53, 54, 56, 59, 60, 62, 65, 66, 68 and 71 stand rejected under 35 U.S.C. §102(b) as being anticipated by Mulhauser (U.S. patent No. 5,766,246). The Examiner contends that Mulhauser discloses a prosthesis and method of implanting a prosthesis that includes a polypropylene mesh layer, a barrier layer as shown in Fig. 3(h), and an edge barrier as shown in Fig. 3(h). Applicants respectfully traverse these rejections.

Mulhauser is directed to an implantable prosthesis 10 having a mesh layer 12 and a semi-rigid frame 14 supporting the mesh layer. (Mulhauser, Col. 3, lines 39-49). As shown in Figs. 2 and 3(h), the frame may be configured to extend over the mesh layer at both the peripheral edge of the mesh layer and the surface margin of the mesh layer adjacent the peripheral edge.

During the interview, the Examiner continued to contend that the frame 14 in Mulhauser is a barrier to adhesions with tissue and muscle, forming both an edge barrier and a surface barrier. More particularly, the Examiner maintained that the frame 14 is an adhesion resistant barrier on the basis that it may be made of a silicone material. Applicants respectfully disagree.

As explained during the interview, Mulhauser does not teach or suggest that the frame 14 has any type of adhesion inhibiting properties. Silicone material does not inherently or necessarily inhibit adhesions. The adhesion resistant properties of a soft tissue repair prosthesis are affected by various factors such as the surface texture and pore size of the material that forms the prosthesis or portions of the prosthesis. (See Eldridge Declaration, paragraph 9). Thus, a prosthesis may be either resistant to the formation of adhesions or promote tissue ingrowth and adhesions depending upon the particular structural characteristics of its material. (See Eldridge Declaration, paragraph 9). For example, a prosthetic material, including silicone, having a surface texture or porosity of approximately 10µm or more is susceptible to adhesions with tissue or muscle. (See Eldridge Declaration, paragraph 9).

Mulhauser provides no teaching or suggestion as to any structural characteristics of the frame that would determine its adhesion resistant properties. The surface texture and porosity of a silicone frame (as well as a molded polypropylene frame) can vary depending on the specific design parameters of the mold used to form the frame. (See Eldridge Declaration, paragraph 10). Therefore, a molded silicone frame can promote tissue ingrowth and adhesions with tissue and muscle. (See Eldridge Declaration, paragraph 10). Thus, the fact that the Mulhauser frame may be injection molded from a silicone material does not necessarily provide a frame that inhibits adhesions to tissue and muscle, such that one of ordinary skill in the art would not consider the Mulhauser frame, even if formed of silicone material, as necessarily being resistant to tissue ingrowth and adhesions to tissue and muscle. (See Eldridge Declaration, paragraph 10).

In the Office Action, the Examiner also contended that the Mulhauser drawings support his position that the frame inhibits tissue ingrowth on the basis that the drawings show a smooth frame. As discussed during the interview, nothing in the figures provide any indication that the frame is adhesion resistant. (See Eldridge Declaration, paragraph 11). As indicated above, the

adhesion resistance of a material implanted in a body depends on the surface texture and porosity of the material and that tissue ingrowth can occur when the surface texture or porosity is approximately 10 $\mu$ m or more. (See Eldridge Declaration, paragraph 11). This amount of surface texture and porosity is microscopic and undetectable with the naked eye. (See Eldridge Declaration, paragraph 11). Thus, simply because the drawings in Mulhauser do not illustrate a rough surface or large pores, the drawings do not indicate that the frame is resistant to tissue ingrowth or adhesions. (See Eldridge Declaration, paragraph 11).

During the interview, the Examiner further contended that the claims merely require a barrier layer and an edge barrier that block the formation of adhesions between the mesh fabric and adjacent tissue and organs, and that the Mulhauser frame would block such adhesions since it would be located between the mesh fabric and adjacent tissue and organs. Applicants respectfully disagree. As discussed during the interview, each of the independent claims (i.e., claims 46, 53, 59 and 65) require that the barrier layer and the edge barrier inhibit adhesions to the barriers themselves. In particular, the claims recite that each barrier inhibits the formation of adhesions with tissue and organs. One of ordinary skill in the art considering the entire specification would readily understand that the claims are limited to adhesion resistant barriers, i.e., barriers that inhibit adhesions to themselves. (See e.g., specification, page 4, lines 18-21 and page 7, lines 15-25).

Notwithstanding the clear meaning of barrier layer as recited in the claims, Applicants have amended each of the independent claims, as discussed during the interview, to further clarify that the barriers are adhesion resistant barriers. In particular, claims 46, 53, 59 and 65 have been amended to recite that the barrier layer and the edge barrier each inhibits the formation of adhesions with tissue and organs "thereto".

Applicants have also amended the claims to further clarify that the first and second sides of the fabric oppose each other and that the barriers either isolate or cover a portion of a side of the mesh fabric and/or a portion of the edge of the mesh fabric. Claims 46 and 65 have been amended to recite that the edge barrier isolates at least a portion of the edge of the mesh fabric. Claim 53 has been amended to recite that the barrier layer covers at least a portion of one of the first and second sides and that the edge barrier covers at least a portion of the edge. Claim 59 has been amended to recite that the barrier layer is covering at least a portion of the first side.

In view of the foregoing, claims 46, 53, 59 and 65 patentably distinguish over Mulhauser, such that the rejections under §102 should be withdrawn. Mulhauser does not disclose an adhesion resistant edge barrier as recited in each of the claims.

Claim 50, claims 54-56, claims 60 and 62, and claims 66, 68 and 71 respectively depend from claims 46, 53, 59 and 65 and are patentable for at least the same reasons. Accordingly, withdrawal of these rejections is respectfully requested.

#### Rejections Under 35 U.S.C. § 103

*Claims 46, 50, 53, 54, 56, 59, 60, 62, 65, 66, 68 and 71*

Claims 46, 50, 53, 54, 56, 59, 60, 62, 65, 66, 68 and 71 also stand rejected under 35 U.S.C. §103(a) as being unpatentable over Mulhauser. In the Office Action, the Examiner contends that it would have been obvious to one of ordinary skill in the art to make the Mulhauser frame smooth to aid and prevent harming surrounding tissue during placement. Applicants respectfully traverse these rejections.

As discussed during the interview, even if one of skill in the art would have been motivated to make the Mulhauser frame smooth to prevent harming tissue, it would not necessarily result in a structure that inhibits adhesions to itself. A structure may have a degree of smoothness that prevents harming surrounding tissue during placement, but nevertheless promotes adhesions thereto. For example, mesh fabric has a degree of smoothness that does not harm surrounding tissue during placement, yet promotes tissue ingrowth and adhesions thereto. Additionally, pore size may affect the tissue adhesion properties of a structure. In this regard, even if a structure has a smooth surface texture, that same structure could still be sufficiently porous so as to promote adhesions thereto. Thus, even were the Mulhauser frame fabricated to be smooth so as to prevent harming surrounding tissue during placement, the smoothness and/or pore size of the material may still promote adhesions to the frame.

During the interview, the Examiner also contended that one of skill in the art would have employed an adhesion resistant material for the Mulhauser frame because such materials were known. Applicants respectfully disagree.

As explained during the interview, the fact that adhesion resistant materials may have been known does not establish that it would have been obvious to modify the Mulhauser frame so as to be fabricated from such a material. Mulhauser employs the frame to maintain the mesh fabric in a desired shape and to provide the implant with a sufficient hoop strength to prevent the

mesh fabric from collapsing into the defect. The purpose of the frame is irrelevant to tissue ingrowth and adhesions. The record lacks any teaching or suggestion that would have motivated one of ordinary skill in the art to fabricate the Mulhauser frame from an adhesion resistant material.

In view of the foregoing, the rejections of claims 46, 50, 53, 54, 56, 59, 60, 62, 65, 66, 68 and 71 under §103(a) in view of Mulhauser are improper and should be withdrawn.

*Claims 51, 52, 55, 57, 58, 61, 63, 64, 69 and 70*

Claims 51, 52, 55, 57, 58, 61, 63, 64, 69 and 70 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Mulhauser in view of Eldridge (U.S. 6,120,539). Applicants respectfully traverse these rejections.


Without acceding to the propriety of the combination as suggested by the Examiner, claims 51 and 52 depend from claim 46 and are patentable for at least the same reasons set forth above. Similarly, claims 55, 57, 58, 61, 63, and 64 depend from claim 53 and are patentable for at least the same reasons set forth above. Claims 69 and 70 depend from claim 65 and are patentable for at least the same reasons set forth above. Accordingly, withdrawal of these rejections is respectfully requested.

**CONCLUSION**

In view of the foregoing amendments and remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is requested to call the undersigned attorney at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicants hereby request any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,

By:   
James M. Hanifin, Jr., Reg. No. 39,213  
WOLF, GREENFIELD & SACKS, P.C.  
600 Atlantic Avenue  
Boston, Massachusetts 02210-2211  
Telephone: (617) 720-3500

Date: May 21, 2004  
x06/09/04